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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/684,682

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07/17/2006

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EXAMINER

GRAFFEO, MICHEL

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/684,682

Applicant(s)

TAPOLSKY ET AL.

Examiner

Michel Graffeo

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-22,24 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22,24 and 34-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Action*

Claims 19-22, 24 and 34-42 are pending and examined.

Applicant has provided arguments for the patentability of claims 19-22, 24 and 34-42 in the response filed 14 April 2006.

Applicant's arguments, see response, filed 14 April 2006, have been fully considered and are persuasive to the extent that the rejection of claims 19-22, 24 and 34-42 under 35 USC §112 and the rejection of claims 19-22, 24 and 34-40 under 35 USC §102 have been withdrawn. Additionally, the Double Patenting rejections over U. S. Patent No. 6,159,498 and U. S. Patent No. 5,800,832 are withdrawn in light of the approved Terminal Disclaimer. Applicant's request that the Double Patenting rejection over copending Application No. 09/069703 be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until an appropriate terminal disclaimer is filed and approved.

Any rejection not specifically stated in this Office Action has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of Election/Restriction***

To clarify the record, the Restriction Requirement mailed 5 March 2002 and responded to on 15 April 2002 was confirmed by the Examiner in the Office Action mailed 19 August 2002. To that extent, claims 34, 36-39 and 41-42 were properly withdrawn from examination. Thereafter, in the Office Action mailed 12 December 2005 the election requirement was effectively removed and all pending claims were examined. Similarly, pending claims 19-22, 24 and 34-42 are currently being examined.

***Claim Rejections - 35 USC § 103***

Claims 19-22, 24 and 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,765,983 to Takayanagi et al. in view of US Patent No. 4,594,240 to Kawata et al.

Takayanagi et al. teach adhesive medical tapes for oral mucosa comprising a support layer composed of an intestine-soluble polymer and a medicament-containing layer composed of a water-soluble polymer containing at least one kind of a steroid or non-steroid antiphlogistic and analgesic medicament (in current claims 19-22, 24 and 34-42; see Abstract), and further comprising a water-soluble polymer such as polyvinylpyrrolidone, sodium carboxymethyl cellulose, hydroxypropyl cellulose (in current claims 22 and 34-40; see col 2 lines 57-end), hydroxypropylmethyl cellulose (claim 36 col 3 line 45) and hydroxymethylethyl cellulose (claim 37 col 3 line 46) and wherein the thickness of the medicament containing layer (which is two layers) is more

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than 20µm and at most 300µm (which is equivalent to 0.02-0.3mm: in claim 20 see col 3 lines 5-18).

Kawata et al. teach the use of hydroxyethyl cellulose and polyacrylic acid (in current claims 19, 22, 34 and 38 in particular; see col 2 lines 41-50) in the flexible pharmaceutical containing sheet (see col 1 lines 4-10).

Although neither references specifically teaches the use of the adhesive for a wound or burn site, one of ordinary skill in the art would have found it obvious to use an anti-inflammatory analgesic agent on a site which requires same.

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Takayanagi et al. and Kawata et al. because Takayanagi et al. cite Kawata et al. and further since both are directed to pharmaceutical carrying sheet shaped muco-adhesives. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

***Response to Arguments - 35 USC §112 and 35 USC §102***

Applicant's arguments filed 14 April 2006 have been fully considered and are persuasive for reasons of record.

***Response to Arguments - 35 USC §103***

Applicant's arguments filed 14 April 2006 have been fully considered but are not persuasive. Although Kawata et al. may allow for a water-insoluble material, the reference also includes embodiments wherein the product comprises water-soluble materials such as gums and cellulose products. Therefore, as combined the references teach the invention as claimed.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-22, 24 and 34-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 15-18 and 33-34 of copending Application No. 09/069703. Although the conflicting

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claims are not identical, they are not patentably distinct from each other because the '703 application claims a water-erodible pharmaceutical carrier device comprising a layered flexible film having a first water-erodible adhesive layer to be placed in contact with a mucosal surface, a second, water-erodible non-adhesive backing layer, and a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodible adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodible non-adhesive backing layer comprises hydroxyethyl cellulose and further wherein the total thicknesses of the adhesives overlap.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5 July 2006

MG

 7/10/06  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER